EMA/178695/2020

European Medicines Agency decision

P/0183/2020

of 15 May 2020

on the acceptance of a modification of an agreed paediatric investigation plan for romosozumab (Evenity), (EMEA-001075-PIP04-15-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0066/2016 issued on 18 March 2016 and the decision P/0247/2018 issued on 15 August 2018,

Having regard to the application submitted by UCB Pharma S.A. on 19 December 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 March 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for romosozumab (Evenity), solution for injection, subcutaneous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to UCB Pharma S.A., Allée de la Recherche 60, 1070 – Brussels, Belgium.

EMA/PDCO/15015/2020
Amsterdam, 27 March 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001075-PIP04-15-M02

Scope of the application

Active substance(s):

Romosozumab

Invented name:

Evenity

Condition(s):

Treatment of osteoporosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

UCB Pharma S.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, UCB Pharma S.A. submitted to the European Medicines Agency on 19 December 2019 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0066/2016 issued on 18 March 2016 and the decision P/0247/2018 issued on 15 August 2018.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 28 January 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of osteoporosis

The waiver applies to:

- the paediatric population from birth to less than 5 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of osteoporosis

2.1.1. Indication(s) targeted by the PIP

Treatment of osteogenesis imperfecta

Treatment of glucocorticoid induced osteoporosis

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

Osteogenesis imperfecta: from 5 years to less than 18 years of age

Glucocorticoid induced osteoporosis: from 10 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	**Study 1** Development of an age appropriate pharmaceutical form
Non-clinical studies	0	Not applicable

Clinical studies	4	**Study 2** Open label, single arm, ascending multiple dose study to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of romosozumab in paediatric patients from 5 to less than 18 years of age with osteogenesis imperfecta (OI) **Study 3** Randomised, double-blind, placebo controlled study to evaluate the efficacy and safety of romosozumab in children with osteoporosis imperfecta in paediatric patients from 5 to less than 18 years of age **Study 4** Randomised, double-blind, placebo-controlled, ascending multiple dose study to evaluate the safety, pharmacokinetics and pharmacodynamics of romosozumab in paediatric patients from 10 to less than 18 of age with glucocorticoid induced osteoporosis (GIOP) **Study 5** Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of romosozumab compared to placebo in paediatric patients from 10 to less than 18 years of age with glucocorticoid-induced osteoporosis

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By May 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of osteoporosis

Authorised indication(s):

- Evenity is indicated in treatment of severe osteoporosis in postmenopausal women at high risk of fracture

Authorised pharmaceutical form(s):

Solution for injection.

Authorised route(s) of administration:

Subcutaneous injection.